REMARKS/ARGUMENTS

Claims 1-73 and 75-87 are pending in the application. Claims 1-66 were previously withdrawn. In this Amendment, claims 67, 70, 73, 76, 77, 79, 80, 83, 84, and 87 are amended. Reconsideration is respectfully requested.

Claim Amendments

Support for the amendments to claims 79, 83, and 87 can be found in the specification at, for example, p. 33, ll. 8-25 and Fig. 21, and p. 45, ll.23-30 and Fig. 29C. Support for the amendments to claims 67, 70, and 73 can be found in the specification at, for example, p. 30, l. 23 to p. 32, l. 10. Support for the amendments to claims 76, 80, and 84 can be found in the specification at, for example, p. 32, ll. 15-28 and Figs. 20A-20B, and p. 43, ll. 23-31 and Figs. 29A-29B. No new matter is introduced.

Claim Objections

Claims 79, 83, and 87 are objected to under 37 CFR 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants disagree.

The objection is based on the conclusion that the microfluidic device cannot include a rotary mixer. Advantageously, embodiments disclosed in the instant application in fact describe such a device. Specifically, a microfluidic device that includes a rotary mixer is discussed in the application at, for example, p. 33, ll. 8-25 and Fig. 21, and p. 45, ll.23-30 and Fig. 29C. To remove any possible doubt regarding the relationship between the rotary mixer and the microfluidic device, amended claims 79, 83, and 87 indicate that lysing can be performed in a rotary mixer of a microfluidic device. Withdrawal of this objection is respectively requested.

35 U.S.C. §112 Rejection

Claims 76, 80, and 84 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is traversed.

Claims 76, 80, and 84 are amended to indicate that a "cross-flow injector structure" includes the intersection of a first microfluidic flow channel and a second microfluidic flow channel.

The Office Action alleges that the term "cross-flow injector structure" is indefinite. Applicants disagree. According to MPEP 2173.02, the essential inquiry pertaining to the definiteness requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of, among other things, the content of the application disclosure. Applicants submit that the instant application disclosure provides ample description of a "cross-flow injector structure." See, for example, p. 32, ll. 15-28 and Figs. 20A-20B, and p. 43, ll. 23-31 and Figs. 29A-29B. Hence, because the application clearly apprises the artisan of the scope of the claim, the notice function is served, and the term "cross-flow injector structure" is not indefinite. However, as noted above, for the purpose of expediting prosecution, claims 76, 80, and 84 are amended. Withdrawal of this rejection is respectively requested.

35 U.S.C. §103 Rejections Over Nelson

Claims 67-69 and 76 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,007,690 to *Nelson et al.* This rejection is traversed.

According to MPEP 2143, to support a *prima facie* case of obviousness it is important to identify a reason that would have prompted the artisan to combine the elements in the way the presently claimed new invention does. The proposed modification of Nelson fails to meet this test.

Amended independent claim 67 is drawn to a method of obtaining nucleic acid from a sample. The method has an isolating step that includes, among other things, allowing the individual biological element or the subset of the biological elements to flow past a first valve of the microfluidic device, creating a segment within the flow channel by actuating the first valve and a second valve of the microfluidic device, and preventing the individual biological element or the subset of the biological elements from exiting the segment past the first valve or the second valve.

The process is not disclosed by Nelson. As indicated in Nelson at Fig. 23 and col. 24 line 12, the sample is manipulated by electrokinetic and magnetic methods. For example, col. 24 line 35-36 describe electromagnetic immobilization of capture beads that contain bound target cells.

Nelson does not teach or suggest an isolating step that includes allowing a biological element to flow past a first valve, creating a segment by actuating the first valve and a second valve, and preventing the biological element from exiting the segment past the first valve or the second valve.

Applicants submit that the Nelson reference would not provide the artisan with a reason to combine elements in the way the presently claimed new invention does, and therefore amended claim 67 is nonobvious. Presently pending claims 68, 69, and 76 depend from independent claim 67, and are therefore patentable by virtue of their dependence from a patentable claim, as well as the nonobvious combination of elements they recite. Withdrawal of this rejection is respectively requested.

35 U.S.C. §103 Rejection Over Nelson in View of Burlage

Claims 70-73, 75, 80, and 84 have been rejected under 35 U.S.C. 103(a) as being unpatentable over *Nelson* in view of U.S. Publication No. 2003/0099928 A1 to *Burlage*. This rejection is traversed.

Amended independent claims 70 and 73 are drawn to methods of obtaining nucleic acid from a sample. The methods have an isolating step that includes, among other things, allowing the individual biological element or the subset of the biological elements to flow past a first valve of the microfluidic device, creating a segment within the flow channel by actuating the first valve and a second valve of the microfluidic device, and preventing the individual biological element or the subset of the biological elements from exiting the segment past the first valve or the second valve.

As noted above, Nelson describes electromagnetic immobilization, but does not teach or suggest an isolation step that involves allowing a biological element to flow past a first valve, creating a segment by actuating the first valve and a second valve, and preventing the biological element from exiting the segment past the first valve or the second valve.

At paragraph [0065], Burlage describes a cell separation step that requires probe labeling. However, Burlage does not teach or suggest an isolation step that involves allowing a biological element to flow past a first valve, creating a segment by actuating the first valve and a second valve, and preventing the biological element from exiting the segment past the first valve or the second valve. Hence, Burlage fails to remedy the deficiencies of Nelson.

Applicants submit that the Nelson and Burlage references would not provide the artisan with a reason to combine elements in the way the presently claimed new invention does, and therefore amended claims 70 and 73 are nonobvious. Presently pending claims 71, 72, 75, 80, and 84 depend from independent claims 70 or 73, and are therefore patentable by virtue of their dependence from a patentable claim, as well as the nonobvious combination of elements they recite. Withdrawal of this rejection is respectively requested.

35 U.S.C. §103 Rejection Over Nelson in View of Unger

Claims 77 and 78 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over *Nelson* and in view of U.S. Patent No. 6,408,878 B2 to *Unger et al.* This rejection is traversed.

As noted above, amended independent claim 67 is drawn to a method of obtaining nucleic acid from a sample. The method has an isolating step that includes, among other things, allowing the individual biological element or the subset of the biological elements to flow past a first valve of the microfluidic device, creating a segment within the flow channel by actuating the first valve and a second valve of the microfluidic device, and preventing the individual biological element or the subset of the biological elements from exiting the segment past the first valve or the second valve.

Unger describes microfabricated elastomeric valve and pump systems. However, the Office Action has not shown that Unger discloses an isolation step that involves allowing a biological element to flow past a first valve, creating a segment by actuating the first valve and a second valve, and preventing the biological element from exiting the segment past the first valve or the second valve. Hence, it has not been shown that Unger remedies the deficiencies of Nelson.

Presently pending claims 77 and 78 depend from amended independent claim 67, and are therefore patentable by virtue of their dependence from a patentable claim, as well as the nonobvious combination of elements they recite. Withdrawal of this rejection is respectively requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

/Nathan S. Cassell/

Nathan S. Cassell
Reg. No. 42,396

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 303-571-4000
Fax: 415-576-0300
NSC/nlm

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